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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,676	06/01/2001	Takashi Miki	Q64808	7681

7590 03/14/2003  
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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	PAPER NUMBER

1624  
DATE MAILED: 03/14/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/870,676	MIKI ET AL.
	Examiner	Art Unit
	Zachary C. Tucker	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 19 February 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,5,6,9-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5,6,9-15 and 17-19 is/are rejected.
- 7) Claim(s) 20 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

***Response to Amendment***

Claims 2-4, 7, 8 and 16 have been cancelled. Claims 1, 5, 6 and 9-15 have been amended. New claims 17-20 have been added.

***Status of***

***Claim Rejections - 35 USC § 112***

In view of the present amendment, filed 19 February 2003, the previously stated rejections of claims 5, 6, 8, 9 and 12-15 under 35 U.S.C. 112, second paragraph, are withdrawn.

***Status of***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The previously stated rejection of claims 1, 5 and 11 under 35 U.S.C. 102(b), as being anticipated by Bourne et al is hereby withdrawn in view of the amendment to claim 1, specifying that the carboxylic acid and organic base are simultaneously added to a solution of a carboxylic acid activating agent of the formula (3).

Bourne et al discloses a process wherein a carboxylic acid and carboxylic acid activating agent are combined first, to which mixture an organic base is then added.

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The previously stated rejection of claims 1, 5 and 9-13 under 35 U.S.C. 102(b), as being anticipated by Urbanski et al is maintained. Claim 15 is no longer anticipated by Urbanski et al, as claim 15 no longer depends from claim 1.

New claim 17 is rejected under 35 U.S.C. 102(b), as being anticipated by Urbanski et al. The presence of an amino group in the carboxylic acid is optional in the process of claim 17, as it is in claim 5 (...*may be substituted with...*).

Urbanski et al discloses simultaneous addition of a solution of carboxylic acid and organic base to a solution of carboxylic acid activating agent – a sulfonic acid chloride - (see page 1229, "Stage 1"):

The procedure is analogous to that which is disclosed in the instant specification in the Examples, wherein a solution of the carboxylic acid and organic base is formed in a vessel, to which vessel the carboxylic acid activating agent is added.

The previously stated rejection of claims 1, 5 and 11 under 35 U.S.C. 102(b), as being anticipated by Gaede is maintained, for the same reason that the Urbanski et al rejection is maintained, which is that the present amendment to claim 1 does not overcome said rejection. Claim 15 is no longer anticipated by Gaede, as claim 15 no longer depends from claim 1.

New claim 17 is rejected under 35 U.S.C. 102(b), as being anticipated by Gaede. The presence of an amino group in the carboxylic acid is optional in the process of claim 17, as it is in claim 5 (...*may be substituted with...*).

The previously stated rejection of claims 1, 5, 9 and 11 under 35 U.S.C. 102(b), as being anticipated by Fife et al is maintained. Claim 15 is no longer anticipated by Fife et al, as claim 15 no longer depends from claim 1.

Fife discloses the process of claim 1, wherein carboxylic acid, organic base, and carboxylic acid activating agent are all three combined simultaneously.

New claim 17 is rejected under 35 U.S.C. 102(b), as being anticipated by Fife et al. The presence of an amino group in the carboxylic acid is optional in the process of claim 17, as it is in claim 5 (...may be substituted with...).

\*\*\*\*\*

The previously stated allowability of claim 6 is withdrawn in view of the following new rejections under 35 U.S.C. 102(b), based on newly discovered art:

Claims 1, 5, 6, 9-15 and 17-19 and are rejected under 35 U.S.C. 102(b), as being anticipated by Benoiton et al, "Preparation of activated esters of N-alkoxycarbonylamino and other acids by modification of the mixed anhydride procedure" J. Peptide Protein Res. vol. 42, pages 278-283 (1993).

Benoiton et al discloses the process of claims 1, 5, 6, 9-15 and 17-19, wherein the carboxylic acid is an N-protected  $\alpha$ -amino acid, the organic base is N-methyl morpholine, and the carboxylic acid activating agent is a chloroformate (page 281 of Benoiton et al).

The mixed anhydrides formed are actually mixed carbonates, but a mixed carbonate is clearly within applicant's definition of a mixed anhydride, as the Examples in the instant specification disclose the synthesis of mixed carbonates.

The procedure in the Benoiton et al reference is analogous to the procedure in Example 1 of the instant specification, where a solution of N-methylmorpholine and carboxylic acid is first formed, to which solution the chloroformate is added (pages 279-280 of Benoiton et al, starting with "*Pure mixed anhydrides 3 for exploratory experiments*").

Claims 1, 5, 6, 9-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramage et al, "A Kinetic Study of Phosphinic Carboxylic Mixed Anhydrides" J. Chem. Soc. Perkin Trans. I, pages 1617-1622 (1985).

The process of claims 1, 5, 6, 9-15 and 17-19 is disclosed on page 1617 of Ramage et al.

N-methylmorpholine, amino acid and phosphinic acid chloride are combined in equimolar amounts. A solution of amino acid and N-methylmorpholine is formed first, to which solution the phosphinic acid chloride is then added.

#### ***Claim Objections/Allowable Subject Matter***

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

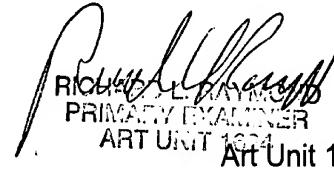
#### ***Conclusion***

This Office action is non-final due to new claim rejections based on new art.

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (703) 305-2050. The examiner can normally be reached Monday-Friday from 7:00am to 3:30pm. If Attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mukund Shah, can be reached at (703) 308-4716. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556 for regular communications and (703) 308-4242 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



  
RICHARD L. GRAY  
PRIMARY EXAMINER  
ART UNIT 1624  
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